

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The U.S. Department of Agriculture.

Verification. The demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

VS. The Veterinary Services Programs of the Animal and Plant Health Inspection Service.

VS select agent and/or toxin. A biological agent or toxin listed in §121.3.

§ 121.2 Purpose and scope.

This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC.

§ 121.3 VS select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to animal health or to animal products.

(b) VS select agents and toxins:

African horse sickness virus;
 African swine fever virus;
 Akabane virus;
 Avian influenza virus (highly pathogenic);
 Bluetongue virus (exotic);
 Bovine spongiform encephalopathy agent;
 Camel pox virus;
 Classical swine fever virus;
Ehrlichia ruminantium (Heartwater);
 Foot-and-mouth disease virus;
 Goat pox virus;
 Japanese encephalitis virus;
 Lumpy skin disease virus;
 Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1);
 Menangle virus;
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia);

Mycoplasma mycoides subspecies *mycoides* small colony (*MmmSC*) (contagious bovine pleuropneumonia);

Peste des petits ruminants virus;

Rinderpest virus;

Sheep pox virus;

Swine vesicular disease virus;

Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3;

Virulent Newcastle disease virus¹

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.²

(2) Recombinant nucleic acids that encode for the functional forms of any toxin listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*; or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) VS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) VS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any VS select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable VS select agents or nonfunctional VS toxins.³

¹A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

²The importation and interstate movement of VS select agents or toxins listed in paragraphs (c)(1) through (c)(3) of this section may be subject to the permit requirements under part 122 of this subchapter.

³However, the importation and interstate movement of these nonviable select agents may be subject to the permit requirements under part 122 of this subchapter.